

Message

From: Faeth, Lisa [Faeth.Lisa@epa.gov]
Sent: 9/27/2018 3:03:40 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

[Fragrances in Your Cabinet Could Be Hiding a Noxious Surprise](#)

By Lauren Coleman-Lochner

Posted Sept. 26, 2018, 2:45 PM

Consumers may be surprised that their favorite scented products could contain some less-entrancing ingredients, according to a new report.

GREENWIRE ARTICLES

Children's health director abruptly put on leave

Kevin Bogardus and Ariel Wittenberg, E&E News reporters

Published: Wednesday, September 26, 2018



Dr. Ruth Etzel, director of EPA's Office of Children's Health Protection, speaking on a panel in 2016. Alaska Community Action on Toxics/YouTube

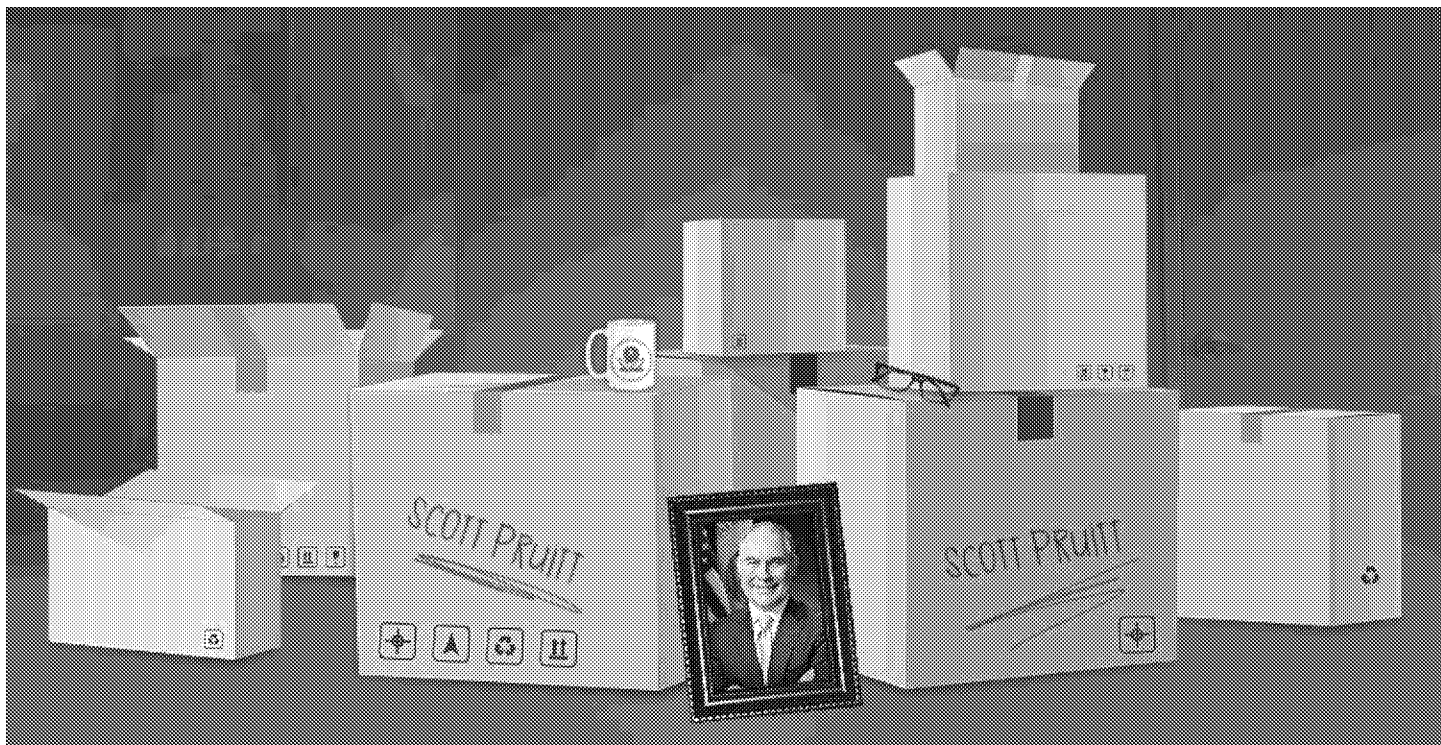
EPA has put the director of its children's health protection office on administrative leave.

Ruth Etzel, a career employee who joined the agency in 2015, was put on leave yesterday, sources told E&E News. The agency declined to provide details about the decision, and it's unclear whether or when she'll return.

The abrupt move has alarmed some agency employees and children's health experts.

<https://www.eenews.net/greenwire/2018/09/26/stories/1060099811>

Pruitt's gone. His stuff isn't



Former Administrator Scott Pruitt's belongings remain at EPA nearly three months after his departure. Claudine Hellmuth/E&E News(illustration); EPA/Wikipedia (Pruitt); Freepik(boxes); Pixabay (mug/glasses); PxHere(picture frame); Pexels/Startup Stock Photos (office door)

Nearly three months after Scott Pruitt's sudden departure from EPA, he still hasn't picked up his belongings.

About a dozen boxes brimming with the ex-EPA administrator's personal items — including frames he had hanging on the wall and items adorning his desk — are being stashed in a storage room at EPA headquarters, according to an agency employee who has seen the boxes.

<https://www.eenews.net/greenwire/2018/09/26/stories/1060099787>

Foreign fellows got \$14.5M from agency — IG

Sean Reilly, E&E News reporter



EPA headquarters in Washington. @EPAScottPruitt/Twitter

During an 11-year period, EPA spent more than \$14 million on fellowships for foreign nationals that could have been used for U.S. citizens or permanent residents, the agency's inspector general said in a report released this morning.

The report, spanning from late 2006 through last year, looked at 166 fellows hosted at EPA laboratories under cooperative agreements awarded to the National Academy of Sciences. Of those, 107, or almost two-thirds of those awards, went to foreign nationals, the report found.

<https://www.eenews.net/greenwire/2018/09/26/stories/1060099809>

INSIDEEPA.COM ARTICLES

EPA Faces 'Firestorm' After Sudden Removal Of Children's Health Chief

The Trump EPA's decision to suddenly dismiss children's health office chief Ruth Etzel days before the start of children's health month and weeks before a meeting of its top advisors, is drawing shock and dismay from the office's supporters, with many warning that the agency is now scrambling to determine how to proceed.

CHEMICAL WATCH ARTICLES

Canadian study links household disinfectant use to weight gain in children

Industry hits back with fierce criticism of research results

26 September 2018 / Academic studies, Biocides, Canada, Cleaning products



Canadian researchers have linked household disinfectant use to child obesity, via their effect on gut bacteria, in a study released last week.

But the paper, widely reported in the media, was met with disappointment by the cleaning products industry which said its "sensational" claims don't hold up.

The researchers profiled 757 infants and the use of cleaning products in the households they grew up in.

When the children were three to four months of age their parents provided fecal samples for each infant. They also completed questionnaires on aspects of their health, home environment and use of cleaning products.

Research assistants then measured the children's weight and height at one and three years of age, and categorised them by their body mass index (BMI).

Roughly 80% of Canadian households use disinfectant products, most often multi-surface cleaners, at least once weekly, the researchers reported in the *Canadian Medical Association Journal*.

And infants living in these households were twice as likely to have higher levels of the bacteria Lachnospiraceae at ages three to four months than children whose homes did not frequently use disinfectants, according to the study.

The scientists also found that, at three years old, those children with higher levels of Lachnospiraceae had a higher BMI than those who do not live in homes that frequently use disinfectants.

Lachnospiraceae are a normal component of our gut microbiota but studies have linked them to higher body fat and insulin resistance in humans and in mice.

The researchers said their findings point to a relationship between disinfectants and the gut bacteria. They noted, however, that more work is needed to confirm that this equals causation.

'Irresponsible' claims

The cleaning products industry called the study findings and media coverage "dramatic" and "unsubstantiated", however.

According to the Household and Commercial Products Association (HCPA): "It is totally irresponsible to say that household disinfectant products cause children to gain weight."

HCPA said the study has multiple limitations and flaws. For instance, it did not collect any data on specific ingredients in the cleaning products. The researchers said in their paper that this is "challenging, as some ingredients are not listed on product labels".

But without knowing a product's chemistry, "a proper assessment of exposure or risk cannot be made", Steve Bennett, HCPA senior vice president of scientific affairs said in a statement.

The Washington, DC-based HCPA represents companies that make and sell \$180bn annually of products used for cleaning, protecting, maintaining, and disinfecting homes and commercial environments, according to its website.

'It is impossible to conclude a product's effect on the child without knowing if and how much/often the child may have been exposed,' Dr Bennett said.

The trade body also slams the study for ignoring confounding factors such as diet, the health of the children at the time of the bacteria measurements, and socio-economic considerations.

"In addition, at no point is there any information on an infant's potential exposure to the products that the parents use," said Dr Bennett. "Frequency of use does not equal exposure and does not include whether the child was present during, or immediately after usage."

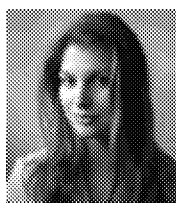
"It is impossible to conclude a product's effect on the child without knowing if and how much/often the child may have been exposed," he added.

The American Cleaning Institute (ACI) echoed this critique, adding that the study's design "ignored all interventions in the children's lives between three months and three years of age".

In a statement, ACI executive vice president Richard Sedlak said the trade body was "disappointed at the sensational claims made by the researchers in this study".

"Proper use of household cleaners and disinfectants is a contributor to infection control and healthy homes. This point was one of many overlooked factors in the reported study," he said.

The ACI, also based in Washington, DC, represents more than 150 companies including manufacturers of household, industrial, and institutional cleaning products, their ingredients and finished packaging; oleochemical producers; and chemical distributors to the cleaning product industry.



Vanessa Zainzinger

Biocides editor

Further Information:

- [Study](#)
- [HCPA statement](#)
- [ACI statement](#)

EPA withdraws rulemaking for 145 Snurs

26 September 2018 / Substance notification & inventories, TSCA, United States

The US EPA has withdrawn 145 TSCA significant new use rules (Snurs) issued under a direct final rulemaking, in response to adverse comments.

The [rules](#), issued in August, address a variety of new substances that were approved for introduction subject to certain restrictions. The Snurs are intended to extend the requirements outlined in the substances' consent orders – which are binding only to the original pre-manufacture notice submitter (PMN) – to others who may use the chemicals in the future.

But a number of businesses, industry groups and NGOs [raised concerns](#) with them. Some noted discrepancies between specific Snurs and the consent orders which they were intended to match, while others took issue with broader concepts common to all 145 rules.

Direct final rules – which are used to move forward non-controversial regulations on an expedited timeline – are required to be withdrawn if met with "significant adverse comment". The agency has consequently withdrawn the rulemaking.

The substances will now be addressed through a proposed rulemaking which was issued in tandem with the direct final rule. The comment deadline for that rule expired on 31 August.

In comments, several groups objected to the EPA's approach of issuing the two rulemakings simultaneously, as this effectively shortened the amount of time to file responses.

But, as of publication, the agency has not extended or reopened the comment period for the proposed rule.

Related Articles

- [EPA issues 145 TSCA significant new use rules](#)
- [US EPA meets resistance on TSCA Snurs proposal](#)

Further Information:

- [Withdrawal notice](#)
- [Proposed rule notice](#)

NGO urges EU states to reject authorisation applications

Key talks on DEHP, chromium trioxide to begin at REACH Committee meeting

26 September 2018 / Alternatives assessment & substitution, Europe, REACH, SVHCs



The European Environmental Bureau is calling on EU member states to reject authorisation applications for uses of two SVHCs.

Its concerns were expressed in a letter to the competent authorities ahead of the REACH Committee meeting on 27-28 September, where preliminary discussions on the applications will begin. The talks will eventually lead to a vote.

In one of the applications, Grupa Azoty Zakłady Azotowe Kędzierzyn and Deza are seeking permission to use bis(2-ethylhexyl) phthalate (DEHP) in PVC articles.

The NGO has said that:

- risks related to the uses of DEHP are not adequately controlled;
- there are suitable alternative substances and technologies for the uses applied for; and
- it has not been demonstrated that the socio-economic benefits of the continued use "outweigh" the risks to human health or the environment.

DEHP was in the first batch of chemicals placed on the authorisation list and according to REACH Article 58 the 'sunset date' was 21 January 2015, the letter said.

However, EEB said, these companies "are still allowed to keep placing this SVHC on the EU market pending the final authorisation decision, hence exposing our citizens and our environment." The NGO added that it regrets the "long unjustified delay" of this decision.

It went on to say that authorities should now acknowledge that DEHP has been identified as an endocrine disrupting chemical and that safer alternatives are available. "Otherwise, the Commission's decision would be based on highly outdated scientific and economic information, communicated by the applicants and Echa's committees at the time of the application (2013)."

Alternatives

The EEB is also urging the committee to turn down an authorisation application by Gerhardt Kunststofftechnik for a use of chromium trioxide.

It said it is "very concerned" about this being granted because Echa's opinion is "outdated" and "disregards" the fact that technology has rapidly developed.

Alternatives are already available, the NGO added, and have been "economically and technically feasible for at least the last two years", according to the manifesto of the Alliance of PVD Providers, submitted to the REACH committee members earlier in September.

Approval would "undermine the credibility" of the process, turn authorisations into "permits to pollute", and create an economic disadvantage for companies that have invested in safer alternatives, the NGO said.

Concerning the DEHP application, it said that one of the applicants – Grupa Azoty – has ceased production of the chemical and moved to non-ortho-phthalate plasticisers, therefore "obviously proving" the availability of alternatives.

It has specifically asked the committee members to:

- reject the authorisation of the Gerhardt application because the applicant has not demonstrated that alternatives are not available; and

- reject the authorisation for the use of DEHP in PVC consumer articles based on REACH Article 60 (paragraphs 2 and 4).

The NGO added that the EU needs to reward the companies making substitution happen, instead of "the laggards" by granting them authorisations to continue the use of SVHCs.

To date the European Commission has not rejected an authorisation application for a use of an SVHC.

Related Articles

- [EU member states agree four phthalates are EDCs for health](#)
- [NGOs say REACH authorisation 'rewards laggards'](#)

Further Information:

- [NGO letter](#)

Oregon amends children's product reporting requirements

Rules to require removal of chemicals of concern from products to be developed in 2019

26 September 2018 / Children's products, Confidentiality & right-to-know, Substances of concern, United States



Oregon has adopted amendments to its children's products reporting rule, which include modifications to its list of reportable substances and other changes to its fees and notification requirements.

The Toxic-Free Kids programme requires manufacturers of children's products to notify the presence of substances included on the state's High Priority Chemicals of Concern for Children's Health (HPCCCH) list above *de minimis* levels.

As part of its triennial review of the programme, the Oregon Health Authority (OHA) added five substances to the HPCCCH list, effective from 1 January. These are:

- bisphenol S (BPS);
- triphenyl phosphate (TPP);
- tris(1-chloro-2-propyl) phosphate (TCPP);
- short-chain chlorinated paraffins (SCCPs); and
- 2-ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB).

And it will remove the following three substances at that time:

- phthalic anhydride;
- octamethylcyclotetrasiloxane (D4); and
- molybdenum and its compounds.

The amendments were based on modifications that Washington made to its Chemicals of High Concern to Children (CHCC) list last autumn. The neighbouring state removed the same three chemicals and added 20 new ones, including these five.

Oregon's list of reportable substances will total 68 when these changes come into force.

Notification, fee changes

The OHA also adopted several modifications clarifying notification requirements and adjusting fee collection.

The updated rule says that notifications must include the number of children's products offered for sale that contain a HPCCCH substance.

And it specifies that only one biennial report must be filed for a specific children's product, and establishes a 'hierarchy' of entities which will be held responsible for this.

The product manufacturer sits at the top of this order of priority, unless that entity has no presence in the US. The distributor is next on the list, provided that it has a domestic presence. If it does not, then the responsibility falls to the importer.

The rule notes that enforcement actions will follow this hierarchy.

Further amendments address fee collection for exemption requests, in line with a bill (HB 5027) adopted into law last year.

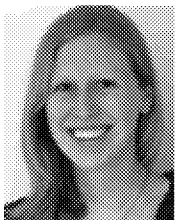
These call for the collection of a \$1,500 nonrefundable fee for a company requesting an exemption from reporting, and an hourly fee of \$200 for the request to be reviewed by the OHA.

These notification and fee changes take effect from 1 October.

Phase 3

The final implementation phase of the state's 2015 Toxic-Free Kids Act calls for manufacturers to remove chemicals of concern from certain children's products, or to request a waiver for their continued use.

The agency intends to start the rule development process for this third phase in the coming year.



Kelly Franklin

North America editor

Related Articles

- [Oregon looks to modify reportable chemicals list](#)
- [Oregon adopts final rule on reporting for Toxic Free Kids Act](#)
- [Washington state requires reporting of 20 additional chemicals in children's products](#)
- [Oregon Toxic Free Kids Act signed into law](#)

Further Information:

- [Amended HPCCCH list](#)
- [Amended notification requirements](#)
- [Toxic-Free Kids programme](#)

US Senate subcommittee holds hearing on PFAS 'crisis'

26 September 2018 / PFCs, United States

A subcommittee for the US Senate Committee on Homeland Security and Governmental Affairs has held a hearing on the federal role in the toxic PFAS chemical crisis.

Panel witnesses to the 26 September meeting included:

- Peter Grevatt, EPA Office of Water;
- Maureen Sullivan, Department of Defense (DOD);
- Linda Birnbaum, National Institutes of Health (NIH); and
- Brian Lepore, Government Accountability Office (GAO).

The hearing came amid mounting public concern and political controversy surrounding the substances.

And it followed a House of Representatives subcommittee hearing on PFAS contamination in the environment on [6 September](#). Environmental groups [told](#) Congress that new PFASs should be banned and called for a halt on continued uses of existing ones.

Related Articles

- [US House committee convenes hearing on PFASs](#)
- [US environmental groups lobby Congress for ban on new PFASs](#)

Further Information:

- [Hearing details](#)

Delaware bans outdoor use of lead-based paints

27 September 2018 / Built environment, Metals, United States

Delaware has become the first US state to ban outdoor lead-based paint. Governor John Carney (D) signed HB 456 into law on 29 August.

The Act, introduced to "protect public health", bans the use of lead paints on structures such as bridges, water towers, playground equipment, highways, parking lots, and utility towers and poles.

The prohibition on any new use of lead-based paints, pigments and coatings will be effective from 1 January 2020. Any use of such items that began before that date will be outlawed from 1 January 2024.

Anyone violating the ban could face a fine up to a maximum of \$10,000 a day, with each day of continued violation considered an additional offence.

The law also requires the state's health and natural resources departments to coordinate efforts to reduce the future effects of the weathering of lead paints already in use outdoors.

Federal ban

The Consumer Product Safety Commission (CPSC) banned the use of lead-based paint for indoor or recreational uses in 1978. But Delaware has been the first to tackle outdoor use.

According to the Act, lead found in paints on outdoor structures threatens the health of workers and the general public because it "causes neurological damage, behavioural and learning disabilities among children, as well as anaemia, high blood pressure, kidney damage and reproductive effects".

There are no safe levels of exposure, the Act says, and no way to reverse the damage caused by lead exposure.

Delaware's ban comes after a two-year campaign by two state residents, environmental advocate Amy Roe and registered nurse Sarah Bucic.

One of the bill's co-sponsors, Representative John Kowalko (D), called it "one of the most important bills to be passed by the state legislature. This landmark legislation will ensure cleaner air, water, and soil and help protect the public against the threat that lead-based products presents."

Related Articles

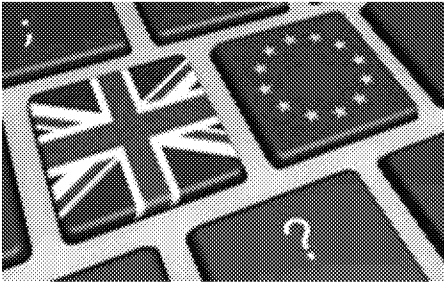
- [US EPA seeks renewed lead paint hazard authorities](#)

Further Information:

- [Bill HB 456](#)
- [Bill details](#)
- [US EPA lead guidance](#)

Brexit threatens chemicals 'chaos' – trade union

Prospect urges participation in Echa, slams UK IT system plans



Livelihoods are "at risk" if the UK does not negotiate "as full an agreement as possible" that maintains its participation in Echa after withdrawing from the EU in March 2019, a trade union has said.

The statement, from union Prospect, was released on 25 September, a day after the UK government published guidance on REACH in the event that Britain leaves the Union without a trade deal. Trade associations and NGOs have voiced their concern about the guidance.

Prospect senior deputy general secretary Sue Ferns said the UK is currently a leading authority in the chemicals sector and "runs the risk of losing its voice in a crucial area".

The trade union represents over 142,000 workers including professionals, managers, technical experts and craftspeople working in a wide range of industries.

Being outside of Echa and regulations like REACH and the Biocidal Products Regulation could bring about a "wider impact" on UK companies producing chemicals and biocidal products, Prospect said, as they may not be able to import what they need to produce products.

In turn this could lead to products such as cleaning products, pest control and preservation not being as easily available for UK consumers."

And even if the UK was able to negotiate limited participation with the EU, Prospect said:

- access to IT systems would be limited and as a non-EU member there could be a fee for using the system;
- the UK could be frozen out of discussions and advice for other European regulators while they are considering new chemicals; and.
- despite having access to the systems, the Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE) would likely not be allowed to veto new chemicals entering the UK, as it can today.

IT system

The CRD is supporting the Department for Environment, Food & Rural Affairs (Defra) on developing IT capability to enable the registration and regulation of chemical substances placed on the national market after a no-deal Brexit.

According to Prospect, the system is "an insurance policy at a considerable cost to the UK taxpayer and government as it might never need to be used". The trade union pointed out that it would not be used if the UK can become an active participant of Echa, albeit without voting rights.

Meanwhile, Prospect raised concerns that plans for a biocides IT system are yet to be confirmed and said it is unclear if the UK will continue to have access to Echa's system.

In August, the HSE claimed that the UK's IT capability is mostly built and "would work" tomorrow if needed. Just over a month later however the UK's National Audit Office warned that the system may need to be "significantly reworked" to allow further long-term enhancements.

Related Articles

- [UK government publishes no-deal Brexit REACH notice](#)
- [Chemical sector voices concerns at UK's no-deal Brexit guidance](#)
- [UK must maintain its voice in EU policy meetings, warns CIA](#)
- [UK starts work on post-Brexit chemicals registration system](#)
- [UK post-Brexit chemicals IT system could be 'ready tomorrow'](#)
- [UK auditor: 'Serious damage' possible from no-deal Brexit](#)

Further Information:

- [Press release](#)

Statistical models account for mixture effects through 'desirability' concept

Epidemiological data used to derive 'guideline values' for risk assessment

27 September 2018 / EDCs, Global, Mixture effects, Risk assessment



A group of scientists based in the US, Sweden and Finland has borrowed from the field of industrial design to create a new class of statistical models to inform risk assessment of mixtures.

The models incorporate the concept of "desirability functions" and deliver "guideline values" for risk based on epidemiological data.

Chemicals legislation typically addresses risks on a substance-by-substance basis and consequently conventional regulatory risk assessment involves consideration of substances in isolation.

Humans and organisms in the environment, however, are frequently exposed to broad mixtures of substances. Furthermore, study after study has shown that the latter can lead to "mixture effects" that are not properly accounted for in conventional assessment.

The desirability function concept is widely used in industry to optimise products and processes. Such a function describes the change in the desirability as the value of a specific variable changes. Multiple functions can be set for a

given product or process, and then the desirability can be optimised by reference to the geometric mean of all the functions.

ACR models

The models, created by Chris Gennings, a biostatistician at the Icahn School of Medicine at Mount Sinai, New York, transfer this concept to risk assessment but with desirability replaced by an absence of adverse effects.

Professor Gennings used data from the SELMA study, which captured prenatal concentrations and later life developmental endpoints from 2,582 pregnant women in Sweden between 2007 and 2010. The data gave a picture of the associations between 11 substances – all known to be endocrine disrupting chemicals (EDCs) – and two developmental endpoints, language development and birth weight.

She used the SELMA data to derive "guideline values" for each relevant substance-endpoint combination. These values correspond to concentrations below which, in theory, adverse effects are not expected if considering the substances in isolation.

She then extended the model to account for the influence of the full set of substances simultaneously. This was achieved by allowing for a mixture effect from the set of chemicals that incorporates an "acceptable concentration range" for each combination of target substance and endpoint.

The scientists say that the ACR models have various limitations relating to assumptions about the required complexity. The work should be considered "proof of concept" but more is required to refine and validate the models.

Nevertheless, Professor Gennings hopes policy makers will engage with the methodology at the core and with the novel idea of deriving guideline values directly from epidemiology data. They should do this, not least because the results were concerning, she said.

The scientists found that their guideline values were typically much lower than their equivalent in published literature and derived from animal testing. They conclude in their paper, published in *Environment International*, that "chemical-by-chemical approaches underestimate risk by a factor that ranges from 1 to 100 for different chemicals".

The research was part-funded by a grant from the US National Institutes of Health and the EU's [EDC-MixRisk project](#), which launched in 2015.



[Andrew Turley](#)

Science editor, Chemical Watch

Related Articles

- [EU research project begins on endocrine disruptor mixtures](#)

Further Information:

- [Paper \(subscription required\)](#)

Echa publishes new guide on safety data sheets and exposure scenarios

27 September 2018 / Europe, Exposure scenarios, Safety data sheets

Echa has published the latest edition of its *Guide on safety data sheets and exposure scenarios*.

The guide is available in 23 European languages as a free download from the EU's online bookshop.

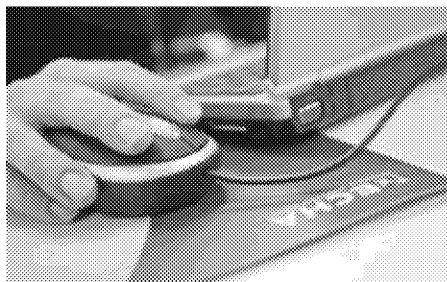
Further Information:

- [Guide on safety data sheets and exposure scenarios](#)

Echa announces major revamp of REACH dossier compliance processes

From January updates will not be considered once draft decision is issued

27 September 2018 / Europe, Substance registration



Echa has announced major changes to its REACH dossier evaluation processes in an effort to increase compliance, improve data quality and encourage collaboration between registrants for ongoing dossier obligations.

From January, the agency says, it will send draft evaluation decisions to all the registrants of a non-compliant dossier, not just the lead registrants.

And, it adds, once a draft decision has been issued it will no longer consider routine dossier updates such as changes to tonnage band, uses or the intermediate status of a registration.

The changes were announced in an Echa webinar and public statement, and come amid growing pressure from regulators and NGOs for better dossier compliance. The agency [revealed](#) in March that over the past decade nearly seven in ten registration dossiers have failed to pass muster.

The European Commission also highlighted the problem in its second REACH Review, in which improvements to dossier updates and evaluation procedures were listed among its proposed [actions](#).

And the issue raised its head at this week's Chemical Watch Enforcement Forum in Brussels, following a presentation on by Jean-Philippe Montfort of law firm Mayer Brown on the recent European Court ruling on the agency's use of statements of non compliance ([Soncs](#)).

Current practice

Echa currently addresses draft evaluation decisions mainly to lead registrants. Individual registrants only receive this information in 'op-outs' – when they submit separate data for a particular use – or if they have high tonnage dossiers.

Up until the last registration deadline, lead registrants were tasked with informing other consortium members in substance information exchange fora (Sief). Information exchange among the co-registrants has been less than ideal, however, leading to gaps in data disclosed in dossiers, according to many observers.

Echa says the change is "timely" as Siefs ceased to exist in a legal context as of 1 June following the last REACH registration deadline. However, registrants are still bound by post-deadline obligations such as dossier updates, joint submissions, new information requests, and cost sharing.

From 1 January, the agency will start checking the compliance of all relevant dossiers for a given substance, and send decisions on testing proposals "to all those registrants intending to rely on the proposed tests to fulfil their information requirement".

It hopes the revision will bring whole joint submissions into compliance, and improve data quality. And, the agency said, it will ensure a level playing field for registrants through "greater certainty and clarity" on obligations, and by addressing opt-outs more systematically.

The changes will also help reduce the number of unnecessary animal testing by making test requests across whole joint submissions, Echa added.

Efficiency changes

As part of the initiative, Echa announced an array of other changes to its dossier evaluation processes. These include:

- streamlining the content of decisions, clear information to registrants about their legal obligations;
- dossier updates must take place before draft decision is issued;
- new online dossier evaluation progress tracker;
- no informal interaction with Echa after the draft decision; and
- registrants asked to speak "with one voice".

Regarding the content of non-compliance Decisions, Echa said it will provide "more focused justifications" for information requests during the evaluation process.

The agency has faced criticism from industry about the difficulty of predicting the compliance standards it applies when evaluating dossiers. The process can take several years before a final decision is issued and registrants are required to submit new data.

In a further step, Echa urged companies to "take a proactive role" and update dossiers before the revised evaluation process is kicked off in 2019.

Justifications for waivers from information requests from Echa, or on adaptations such as category or read-across approaches will also not be considered after a draft decision is made, it said. From that point, an update will be taken into account only if:

- it brings the dossier into compliance; or
- to avoid unnecessary animal testing.

Among other changes, the agency will no longer offer informal interaction with registrants after a draft decision is sent, as it says "many already know the process". This may be replaced by earlier interaction before the start of evaluation when addressing categories or groups of substances.

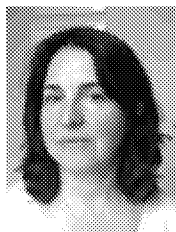
The new evaluation regime also calls for registrants to coordinate their responses to Echa, and "speak with one voice" during the entire process.

'Crystal clear' decisions

The European Chemical Industry Council said the initiative was "helpful" for registrants and reflected the reality of the post-2018 REACH era without Siefs as legal entities.

"It will be crystal clear who will have to contribute to what study, which will reduce the number of discussions on cost-sharing," Cefic said.

However, some of its members are concerned that Echa may no longer consider changes related to the tonnage band after a draft decision has been notified, it said, and it is checking "whether this does not contradict current legislation".



Clelia Oziel

Reporter

Related Articles

- [Decade of REACH dossier evaluation reveals 70% non-compliance](#)
- [EU publishes delayed second REACH Review](#)
- [Echa 'will not appeal' EU court ruling on Soncs](#)
- [Directors' Contact Group publishes post-2018 Sief recommendations](#)

Further Information:

- [Echa statement](#)
- [Webinar](#)

CIA, Cefic advise companies on UK out-of-REACH scenario

Comprehensive paper spells out possible actions for British, EU/EEA firms

27 September 2018 / Europe, REACH, Substance registration, United Kingdom



The UK's Chemical Industries Association and Cefic have produced a joint briefing note containing advice for companies in the event of Britain leaving EU REACH after Brexit.

In a "worst-case scenario" – where a trade deal is not agreed between the UK and the EU – REACH could stop applying to Britain from 30 March 2019; or from 1 January 2021 if a transition period is negotiated.

The note comes a few days after the UK government published its no-deal Brexit technical notice for the chemicals industry.

The CIA and Cefic provide guidance on three areas:

- considerations for UK-based businesses for maintaining access to the single market;
- considerations for EU-based companies with UK supply and trade relationships; and
- implications of a future UK REACH for UK and EU27/EEA companies.

To ensure continued validity of existing REACH registrations in the EU, they say, it is important that companies identify substances/mixtures impacted by Brexit and their role in the supply chain.

If a substance is manufactured by UK and EU legal entities from the same company and both hold valid registrations, the EU entity could act as importer of the UK product.

In this case, the EU legal entity's existing registration would need to be updated to reflect any additional volume in the dossier, the note adds.

"Please be mindful that higher tonnage bands may be reached and further testing required as a consequence. An only representative (OR) would not need to be appointed in this case and transfer of registrations would not be required. Such a scenario however would not be available to companies which only have sites in the UK."

In the case of mixtures, UK formulators may need to track raw materials imported from the EU to confirm future "re-import" to EU status.

Registration transfers

In an out-of-REACH scenario, UK registered companies wishing to continue selling their chemicals in the EU would need to transfer their registration to an only representative based in the trade bloc.

However, UK manufacturers and importers will need to maintain their registrations in the UK to be able to continue to manufacture/import in the country until REACH no longer applies.

The Echa website says that the possibility of transferring existing registrations "immediately" before the withdrawal date will be put in place for registrations held by UK manufacturers and practical steps will be clarified in due course.

The CIA and Cefic say UK companies "should assume" that in a worst-case scenario their accounts in Echa's REACH-IT system may have to be deactivated from the date REACH stops applying in Britain, "so transfer of registrations should be completed before the UK leaves the regime".

According to the note, Echa is setting up a contractual agreement to appoint an OR, which contains a "suspensive conditional clause" stipulating that the appointment takes effect on the date EU withdrawal is executed.

In the case of UK importer registrations – Echa says it is not possible to transfer a registration of a British importer to a newly appointed OR. In this case, non-EU manufacturers may appoint an EU-based OR. However, the latter would then need to submit a new registration for the substance.

Additionally, the CIA and Cefic say they expect companies based outside the UK (including EU businesses) will be able to appoint UK-based representatives if they wish to relieve British customers from registration obligations under a UK REACH – although this has not yet been officially confirmed.

They urge companies to review consortia agreements to prepare for the potential future transfer of dossier rights to an EU subsidiary or representative.

Should a no-deal scenario transpire, the associations say they will continue to engage with authorities on both sides to ensure REACH compliance challenges faced by UK and EU business are minimised.



Luke Buxton

Europe desk editor

Related Articles

- [UK government publishes no-deal Brexit REACH notice](#)
- [Chemical sector voices concerns at UK's no-deal Brexit guidance](#)
- [ORO publishes new Brexit advice for only representatives](#)

Further Information:

- [Briefing note](#)

US EPA round-up

27 September 2018 / TSCA, United States

TSCA 'not likely to present an unreasonable risk' finding

The US EPA has issued a "not likely to present an unreasonable risk" finding under TSCA section 5(a)(C) for a new chemical substance that was the subject of a pre-manufacture notice (PMN).

The determination – for benzenesulfonic acid, (alkenediyl)bis[(((hydroxyalkyl)amino)-(phenylamino)-triazin-2-yl)amino]-, N-(hydroxyalkyl) derivs, salts – will allow it to go to market without restriction. The agency cites a risk assessment in support of the decision.

The substance, which was the subject of PMN P-17-0332, is used industrially as an optical brightener in paper applications.

The EPA's determination says that although it estimates that the substance could be very persistent, it has low potential for bioaccumulation, "such that repeated exposures are not expected to be cumulative".

Based on test data, the agency says the chemical has moderate environmental and low human health hazard. It therefore says the substance is not likely to present an unreasonable risk under the conditions of use.

Company access to TSCA CBI

The EPA has granted General Dynamics Information Technology access to information submitted to the agency under all sections of TSCA. Some of this, the EPA says, may be claimed or determined to be confidential business information (CBI).

The company, from Fairfax, Virginia, has been contracted to assist the Office of Research and Development (ORD) and the Office of Pollution Prevention and Toxics (OPPT) with:

- Toxics Release Inventory (TRI) updates;
- risk assessments for both new and existing industrial chemicals;
- identifying chemicals of interest in screening information data set (SIDSs); and
- support of assessment/prioritisation efforts for existing chemicals under the revised TSCA and the Chemical Assessment and Management Plan (CHAMP).

GDIT has been allowed access to CBI from 25 September until 31 January 2023, when its contract will come up for renewal.

Senate oversight hearing on regulatory science

A subcommittee of the Senate Committee on Environment and Public Works (EPW) is holding a hearing on the EPA's use of science to inform regulation decisions on 3 October.

The hearing, billed as: Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation, will be conducted by the EPW's subcommittee on Superfund, waste management, and regulatory oversight.

Scientific integrity consultation

The agency has begun a consultation on a proposed rule aimed at addressing scientific integrity among the contractors it employs to carry out work.

The current policy is based on a memorandum from March 2009 that called on the director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to "develop policies to ensure all scientific work developed and used by the government is done so with scientific integrity."

This proposed rule requires any contractor to ensure all personnel within its organisation – including subcontractors and consultants – that carry out scientific activities or use scientific information to perform advisory and assistance services, understand their compliance responsibilities regarding the agency's scientific integrity policy.

As well as listing contractor obligations, the proposed rule prohibits the intimidation or coercion of scientists to alter scientific findings. It also has a "whistleblower" clause that bans "retaliation or other punitive actions toward employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion".

Comments must be submitted by 26 November.

Children's environmental health meeting

The EPA has called a meeting of the committee that advises it on science, regulations, and other issues relating to children's environmental health.

The Children's Health Protection Advisory Committee (CHPAC) will meet in Washington, DC, on 11-12 October.

Further Information:

- [New substance determination](#)
- [PMN reviews](#)
- [CBI access](#)
- [Senate hearing](#)
- [Scientific integrity consultation](#)
- [CHPAC meeting](#)

European Environment Agency: mercury still a 'significant risk'

27 September 2018 / Europe, Metals

Mercury continues to present a significant risk to the environment and human health, the European Environment Agency said in a report published this month.

While the main source of new emissions is coal burning, about half of the mercury deposited in the environment comes from outside Europe.

The substance, the report says, poses the biggest risk in rivers, lakes and oceans where it takes a highly toxic form that is absorbed by animals, including fish.

Entitled *Mercury in Europe's environment – A priority for European and global action*, the report is available for free via the EEA's website.

The EEA is an agency of the European Union that gives "independent information on the environment for those involved in developing, adopting, implementing and evaluating environmental policy, and also the general public".

A new EU mercury Regulation [came into force](#) in July.

Related Articles

- [EU publishes mercury Regulation](#)

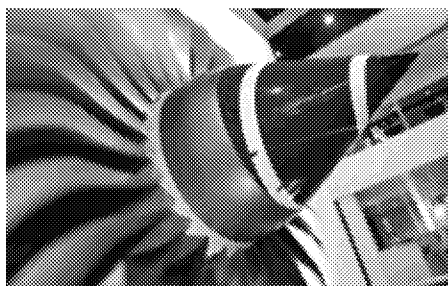
Further Information:

- [EEA report](#)

Industry flags up concern with TSCA chlorinated paraffin Snurs

Five-year notification requirements could bring downstream uncertainty

27 September 2018 / Aerospace, automotive & engineering, Substance notification & inventories, United States



Business groups throughout the value chain are protesting the US EPA's plan to impose time-based significant new use rule (Snur) requirements on a set of medium- and long-chain chlorinated paraffins (MCCPs and LCCPs).

The concern relates to ten Snurs included in a recent [batch of 27](#), issued under TSCA on 17 August. The new rules aim to align requirements imposed on those substances' original pre-manufacture notice (PMN) submitters to others who may use the chemicals.

But several groups filed adverse comments on the EPA's plans to define as a 'significant new use' the manufacture of each of ten widely used MCCPs and LCCPs for more than five years.

Downstream users, including the Independent Lubricant Manufacturers Association (ILMA) and the Aerospace Industries Association (AIA), said that the substances serve critical roles in applications such as aircraft and jet engine fasteners and in lubricant mixtures, and that the rules would impose uncertainty as to their continued availability.

And the Chemical Users Coalition (CUC) – which represents organisations such as Airbus, Boeing, Lockheed Martin and Intel – added that pausing the use of a substance after five years "is likely to disrupt not only the operations of the manufacturer, but also the operations of downstream processors and users of these substances".

Several industry groups have also questioned whether the agency has the authority to regulate the use of these existing substances under section 5 of TSCA: the new chemicals programme.

Background to chlorinated paraffin issue

Unlike typical PMNs, which correspond to substances entering the US market for the first time, the notices to which these ten Snurs relate are for substances that have already been in commerce for decades.

The substances had been brought to market under two 'categorical' entries for chlorinated paraffins, which were included on the original 1979 TSCA inventory. But in 2009, the EPA brought enforcement action against a chlorinated paraffin manufacturer and an importer, objecting that their substances were not captured in these non-specific listings, and therefore not included on the inventory.

A 2012 consent decree entered in a federal district court resolved this issue. It allowed the companies to continue to produce the chemicals, provided they submit PMNs for them, which they did that same year.

Some five years later, the EPA approved the PMNs and imposed a consent order on each. Among their requirements were that the PMN submitter must discontinue the substances' manufacture after five years, unless they have submitted new environmental test data.

The recent Snurs apparently represent the EPA's effort to extend this consent order requirement to the rest of the marketplace. If adopted, it would require the submission of a significant new use notice (Snun) for use of the substance beyond that five-year period.

The EPA could, presumably, then use the test data it will have received by then to determine if those uses pose an unreasonable risk.

Industry concerns

The Chlorinated Paraffins Industry Association (CPIA) was among groups who requested that the agency amend the Snurs in order for them to be "clear and effective".

The CUC said, for example, that it was not clear when the five-year period begins: if it is from the date of the Snur becoming effective, or from when an individual entity begins manufacturing.

It also sought further information on what obligations would be applicable to processors.

The American Chemistry Council (ACC), meanwhile, argued that the EPA may not treat these substances as typical PMN chemicals, and that it cannot assert that uses which have been ongoing for considerably more than five years can be counted as "new".

But it noted that the EPA may use section 6 – which covers existing chemicals – to conduct a risk evaluations on them. MCCPs and LCCPs are both included on the 2014 update to the TSCA [work plan](#), a group of substances which the agency is directed to "give preference to" when selecting high priority substances, the ACC added.

The ILMA and AIA also recommended that the EPA address the substances through section 6 of TSCA.

Rulemaking process

The EPA issued the Snurs as both a direct final rule and a proposed rule. If adverse comments are received with respect to the former, the EPA must withdraw those portions of the rule and address them through the more formal proposed rulemaking process.

Beyond the concerns raised on these chlorinated paraffins, the EPA also received feedback from the Environmental Defense Fund (EDF) raising issue with the full set of 27 substances, in line with its [comments](#) on [145](#) other Snurs.

The agency is therefore likely to withdraw the entire direct final rule, as it has done with the first set of rules issued in August.

Chlorinated paraffins subject to proposed Snurs

- alkanes, C₂₀₋₂₈, chloro;
- slack waxes (petroleum), chloro;
- hexacosane, chloro derivs. and octacosane, chloro derivs.;
- alkanes, C₂₀₋₂₄, chloro;
- alkanes C₁₄₋₁₆, chloro;
- tetradecane, chloro derivs.;
- octadecane, chloro derivs.;
- alkanes, C₁₈₋₂₀, chloro;
- alkanes, C₁₄₋₁₇, chloro; and
- alkanes, C₂₂₋₃₀, chloro.



Kelly Franklin

North America editor

Related Articles

- [EPA issues 27 TSCA significant new use rules](#)
- [US EPA updates work plan chemical assessment programme](#)
- [US EPA meets resistance on TSCA Snurs proposal](#)
- [EPA issues 145 TSCA significant new use rules](#)
- [EPA withdraws rulemaking for 145 Snurs](#)

Further Information:

- [Docket](#)
- [Proposed rule](#)
- [AIA comments](#)

- [ILMA comments](#)
- [CUC comments](#)
- [CPIA comments](#)
- [ACC comments](#)
- [EDF comments](#)

Echa round-up

27 September 2018 / Alternatives assessment & substitution, Classification, Europe, Labelling, REACH

Comments sought on waste framework Directive database

Echa is consulting on a first draft scenario for a new database on candidate list substances in articles. The task is under the revised waste framework Directive that entered into force in July.

The database will contain information submitted by companies producing, importing or supplying articles that contain candidate list substances. They need to submit this information for articles placed on the market from 5 January 2021.

It has the aim of strengthening good supply chain communication as foreseen under REACH and contributes to the EU's circular economy package.

Primary users of the database will be waste treatment operators and consumers.

The feedback deadline is 9 October.

BOA decisions on substance evaluation appeals published

The Board of Appeal has published decisions in which two separate appeals were brought against the same Echa decision concerning 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol.

In both cases, A-007-2017 and A-008-2017, the appellants challenged the requirement to provide information on an extended one-generation reproductive toxicity study (Eogrts). The BoA annulled this part of the contested decision for both on the grounds that Echa had made a mistake in the choice of procedure to request that information.

As the Eogrts was a standard information requirement at the time the contested decision was adopted, the agency should have examined whether requesting the study under substance evaluation prejudiced the rights of any of the registrants.

In particular, it should have taken into account that the relevant registrations had been submitted at different tonnage levels.

Webinar on major new version of Iuclid

Echa is running a webinar on 31 October (11:00-13:00 EET, GMT +2) to introduce a major new version of Iuclid, available from the end of October.

The webinar is an opportunity to learn about the changes and pose questions to the agency's experts.

luclid 6.3 features a completely new user interface, in addition to what already exists, that runs in a standard web browser with no need to install any other software. This provides a more streamlined user experience, while still containing the basic features needed to prepare a REACH, CLP or BPR dossier.

There are also changes to the luclid format, including the latest OECD harmonised templates, specific elements for microorganism datasets and support for European poison centre notifications.

CLH intentions and proposals

Echa has received two new proposals to harmonise the classification and labelling (CLH) for:

- cinnamaldehyde; and
- methyl methacrylate.

And the following CLH intentions for:

- undecan-2-one;
- chloromethane;
- reaction products of boric acid with didecylamine and ethylene oxide;
- 1-[2-({[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy}methyl)-3-methylphenyl]-4-methyl-1,4-dihydro-5H-tetrazol-5-one;
- (3E)-dec-3-en-2-one; and
- [S-(Z,E)]-5-(1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl)-3-methylpenta-2,4-dienoic acid.

No REACH registration data published until 2019

The agency has said it will not be publishing any new REACH registration data until January 2019.

This is to allow for development work to update the dissemination system, required because of the launch of the new version of luclid at the end of October.

At the same time the agency will re-process old submissions in accordance with the policy announced in April 2016.

From January it will publish non-confidential data from dossiers submitted or updated between October and December 2018 and resume regular updates.

REACH-IT unavailable

The REACH-IT tool will be unavailable from 12:00pm Friday 28 September to 10:00am Monday 1 October (Helsinki time) because of system maintenance.

Committees' Opinions on applications for authorisation

The consolidated opinions of the Committees for Risk Assessment (Rac) and Socio-economic Analysis (Seac) are available on the agency's website for the following applications for authorisation:

- three uses of chromium trioxide by Hapoc;

- two uses of pentazinc chromate octahydroxide by Aviall Services and Finalin;
- one use of dichromium tris(chromate) by Wesco Aircraft EMEA; and
- one use of strontium chromate by Wesco Aircraft EMEA, PPG Central (UK) in its legal capacity as only representative of PRC DeSoto International, and Cytec Engineered Materials in its legal capacity as only representative of Cytec Industries.

Management Board reappoints chair, confirms Hansen's role

Echa's Management Board has renewed Sharon McGuinness' mandate as chair and confirmed the appointment of Bjorn Hansen as Echa executive director.

Mr Hansen completed the nine-month probation period for his role with an initial mandate of five years.

Further Information:

- [Feedback on WFD database](#)
- [BoA Decision in case A-007-2017](#)
- [BoA Decision in case A-008-2017](#)
- [Registration lucid webinar](#)
- [Registry of intentions](#)
- [Adopted Opinions](#)

EU SDS enforcement project gaining pace

27 September 2018 / Enforcement, Europe, REACH

Echa Enforcement Forum's [project](#) to identify and resolve issues with safety data sheet (SDS) quality will take a step forward next week when a working group sits down to identify trends and pinpoint the biggest deficiencies for follow-up action in 2019.

The meeting is part of the REACH-En-Force (Ref-5) initiative involving national enforcement authorities and industry representatives who have compiled a large database about the quality of SDS information. Sinead McMickan, Echa's enforcement forum vice chair, told the Chemical Watch Enforcement Summit Europe 2018 this week.

"We are aware there are many problems with poor quality safety data sheets in the chain, despite their age – they're nearly 30 years old now – and yet, the information that is coming out of them is quite poor. And it is worrying," Ms McMickan told delegates at the Brussels' conference.

Once the trends and biggest deficiencies are identified, the group will propose solutions which will be implemented and monitored.

"We are gathering data, and it will be next year until we really see some action coming out of this," Ms McMickan added.

She also outlined several of Echa's REACH enforcement projects and priorities for the future which include:

- the REF-8 project focusing on [internet sales](#) and restrictions, with a working group to start in early 2019 and be operational in 2020;
- drafting of the final report for the prior informed consent (Pic) Regulation project looking at export notification requirements;
- a pilot project focused on cooperation with customs authorities; and
- a survey to determine practices and interaction between REACH and occupational safety and health (OSH) inspectors to remove overlaps and improve coordination of national enforcement authorities.

Related Articles

- [EU enforcement project to target quality of SDSs](#)
- [Enforcement project to check EU internet chemical sales](#)

Further Information:

- [Echa draft strategic plan for 2019-2023](#)
- [Echa guide on safety data sheets and exposure scenarios](#)
- [Chemical Watch Enforcement Summit Europe programme](#)

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OTHER ARTICLES

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Black Enterprise

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[Toxic Chemicals in Toys Affect Households](#)

Asharq Al-awsat English

The study said that in the course of time, these materials transform into "**toxic dust**" that scatter around the house **and** affect its residents, which may ...

[Landmark BCPP Report Reveals Secret Fragrance Chemicals in Beauty, Personal Care, and ...](#)

GlobeNewswire (press release)

Today Breast Cancer Prevention Partners (BCPP) released a landmark report — Right to Know: Exposing **Toxic Fragrance Chemicals** in Beauty, ...

How retailers benefit from participating in ChemSec's Marketplace

Safer Chemicals, Healthy Families (press release) (blog)

On the one hand, we noticed a strong drive from progressive retailers and brands to substitute **hazardous chemicals** in products and supply chains ...